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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,534	09/01/1999	THOMAS M. KUNDIG	C9015-2007	2743

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EXAMINER

HAYES, MICHAEL J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 12/01/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/380,534

Applicant(s)

KUNDIG, THOMAS M.

Examiner

Michael J Hayes

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 22-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 39-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 7, 8, 9, 10, 14, 39, 43-52, 55-59, 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by MARTINS et al. (U. S. Patent No. 4,455,142). Martins discloses a method of inducing and/or sustaining a CTL response by continuously delivering a single or multiple antigen(s) to a mammal (col. 3, lines 57-68; col. 4, lines 10-40).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- ~~4.~~ Claims ~~2, 3, 5, 6, 11, 12, 13, 15, 16, 20, and 21~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINS as applied to claims 1 and 4 above, and further in view of KUNDIG (Science. 268:1343-1347). Martins discloses the claimed innovation except for delivering the antigen directly to the lymphatic system, treating cancer, using a cytokine, or an osmotic pump. Kundig discloses that delivering an antigen with a cytokine is well-known in the art, but that delivery can also be made directly to the cytokine-rich lymphatic system. It would

Art Unit: 3763

have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kundig in the invention of Martins in order to provide a tumor vaccination strategy to make tumors immunogenic. It is notoriously well-known in the art to use osmotic pumps to deliver a desired therapeutic composition.

5. Claims 17, 18, 19, 41, 42, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINS as applied to claims 4, 39, and 48 above, and further in view of FALO, Jr, et al. (U. S. Patent No. 5,951,975). Martins discloses the claimed invention except for delivery of a MAGE-1 antigen. Falo teaches utilizing a MAGE-1 antigen to induce a CTL response in a patient (col. 4, lines 20-37). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Falo in the invention of Martins in order to stimulate CTL production and destruction of tumor cells without having to identify antigens for each specific tumor (col. 3, lines 38-45).

6. Claims 40 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINS as applied to claims 39 and 59 above, and further in view of EBERLEIN et al. (U. S. Patent No. 5,550,214). Martins discloses the claimed invention except that that the polypeptide antigen is 8-10 amino acids. Eberlein teaches the use of polypeptide antigens of 9 and 10 amino acids (col. 2, lines 29-61; col. 3, lines 20-28; col. 17, line 56 - col. 18, line 60). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Eberlein in the invention of Martins in order to initiate immune responses against tumor cells only (col. 2, lines 18-23).

Art Unit: 3763

Response to Arguments

7. Applicant's arguments with respect to claims 1-21, 39-65 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be contacted at (703) 308-5181. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.



Michael J. Hayes
17 November 2001

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.